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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---------------------------------|-------------|----------------------|-----------------------|------------------|
| 10/663,362 | 09/16/2003 | Roger Massengale | IFLOW.149A | 1650 |
| 20995 | 7590 | 10/02/2007 | EXAMINER | |
| KNOBBE MARTENS OLSON & BEAR LLP | | | KOHARSKI, CHRISTOPHER | |
| 2040 MAIN STREET | | | ART UNIT | PAPER NUMBER |
| FOURTEENTH FLOOR | | | 3763 | |
| IRVINE, CA 92614 | | | | |
| NOTIFICATION DATE | | DELIVERY MODE | | |
| 10/02/2007 | | ELECTRONIC | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com
eOAPilot@kmob.com

Office Action Summary

| | | | |
|-----------------|-------------------------|--------------|-------------------|
| Application No. | 10/663,362 | Applicant(s) | MASSENGALE ET AL. |
| Examiner | Christopher D. Koharski | Art Unit | 3763 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 18 July 2007.
2a) This action is FINAL. 2b) This action is non-final.
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1,2,4-16 and 25-27 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) Claim(s) _____ is/are allowed.
6) Claim(s) 1,2,4-16 and 25-27 is/are rejected.
7) Claim(s) _____ is/are objected to.
8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
4) Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
5) Notice of Informal Patent Application
6) Other: _____.

DETAILED ACTION

Response to Amendment

Examiner acknowledges the RCE filed 7/18/2007 in which claims 1 and 6-7 were amended and new claims 25-27 were added. Currently claims 1-2, 4-16 and 25-27 are pending for examination in this application.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4-5, 7-9, 12-15 and 26-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Reed, Jr. (5,827,530). Reed, Jr. fillable patch for dermal or transdermal delivery.

Regarding claims 1, 4-5, 7-9, 12-15 and 26-27, Reed, Jr. discloses a fluid medication delivery device comprising a fluid impermeable layers (26, 14), a fluid semi-permeable layer (16, 28) wherein the two layers define a fluid reservoir space in between, a fluid inlet (32,34) comprising a valve that allows for fluid entry wherein the device is capable of perfusing liquid through the permeable layers when pressure is imparted on the fluid (col 3 ln 34-67, col 4 ln 1-44) (Figure 2), said fluid inlet adapted to permit said fluid delivery device to be selectively connectable to a connector (38) for a continuous supply of fluid (syringe, figure 2), said delivery device (port 32, 34) being adapted to selectively secure said connector in the radial and axial direction.

Additionally, the valve is configured to allow fluid to enter the reservoir but prevent fluid from exiting the fluid reservoir (col 4, ln 1-10) wherein the fluid reservoir comprises walls that are all heat sealed together (18, 20, 23) and also comprises a segmenting element (40) that defines a separate space in the reservoir with interconnected regions (Figure 2).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 2, 6, 10-11 and 16 are rejected under 35 U.S.C 103(a) as being unpatentable over Reed, Jr. in view of Deniega et al. (6,350,253). Reed, Jr. meets the claim limitations as described above except for the specific membrane pore sizes and membrane materials.

However, Deniega et al. teaches a catheter for uniform introduction of medication.

Regarding claims 2, 6, 10-11 and 16, Deniega et al. teaches a drug delivery device (20) catheter comprising a catheter (24) for long-term continuous delivery of medication (36) comprising a semi-permeable membrane with varying pore sizes from 0.1 microns to 1.2 microns (col 8, ln 5-30) composed of several materials including polysulfone, polyethersulfone, nylon, and polyvinylidene di-flouride (col 7, 65-70, col 8, ln 1-5) (Figures 1 and 5-6).

At the time of the invention, it would have been obvious to use the membrane materials of Deniega et al. with the system of Reed, Jr. in order to use an advantageous membrane to minimize the flow of bacteria into the reservoir and allow for optimal drug delivery. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Deniega et al. (cols 1-2).

Claim Rejections - 35 USC § 103

Claim 25 is rejected under 35 U.S.C 103(a) as being unpatentable over Reed, Jr. in view of Weston et al. (4,605,309). Reed, Jr. meets the claim limitations as described above except for the luer coupler connector on the fluid medication delivery device.

However, Weston et al. teaches a transdermal infusion device.

Regarding claim 25, Weston et al. teaches a transdermal patch (12) for with a semi-permeable layer (15) (Figure 3) and fluid impermeable pouch (10,16) with a fluid inlet (24) connected to a connector (18) which is a luer connector (Figures 1-5).

At the time of the invention, it would have been obvious to add the luer connector of Weston to the system of Reed, Jr. in order to add a readily connectable universal well known connector for fluid transfer. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Weston et al. (cols 1-2).

Response to Arguments

Applicant's arguments filed 7/18/2007 have been fully considered but they are not persuasive. Applicant's Representative asserts that the Reed, Jr. (5,827,530) does not disclose a delivery device to be selectively connectable to a connector for a supply of fluid, said delivery device adapted to be selectively secure said connector is the radial and axial direction and an internal segmenting wall.

Examiner has fully considered applicant's arguments but they are not persuasive. It is examiners position that given a careful reading, the claims do not distinguish over the prior art of record.

Examiner asserts that the Reed, Jr. does disclose the delivery device as claimed by Applicant (see rejection above). Examiner further asserts that the fluid inlet connections (32, 34) are capable of meeting Applicant's claim limitation of securely fastening a connection element (the syringe needle (38)) in a radial and axial fashion by inserting the needle into the rubber septum port. Additionally, the identified internal wall (40) meets the claim limitation of a segmenting wall element, the wall element *may be* free floating or secured, however Applicant claims neither of these, merely an internal

segmenting wall, under the broadest reasonable definition the shield creates a segmented region within the reservoir and therefore meets the claim. The limitations described by Applicant's Representative are merely functional recitations and where the prior art reference is inherently capable of performing the function described in a functional limitation, such functional limitation does not define the claimed apparatus over such prior art reference, regardless of whether the prior art reference explicitly discusses such capacity for performing the recited function, see *In re Ludtke*, 441 F.2d 660, 169 USPQ 563 (CCPA 1971). Regarding the fluid inlet connector being capable of allowing continuous fluid delivery the rubber septum is capable of allowing tubing to be hooked up for this purpose, although not disclosed by the reference. Additionally, it is well established that a recitation with respect to the manner in which an apparatus is intended to be employed, i.e., a functional limitation, does not impose any structural limitation upon the claimed apparatus which differentiates it from a prior art reference disclosing the structural limitations of the claim, see *In re Pearson*, 494 F.2d 1399, 181 USPQ 641 (CCPA 1974).

The prior art of record teaches all elements as claimed and these elements satisfy all structural, functional, operational, and spatial limitations currently in the claims. Therefore the standing rejections are proper and maintained.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Koharski whose telephone number is 571-272-7230. The examiner can normally be reached on 7:30am to 4:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Date:

9/25/07


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